DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved; OMB No. 0910-0124
Expiration Date: November 31, 2001
See Reverse of Part 3 for OMB statement.

DATE SUBMITTED

PRODUCT LICENSE APPLICATION FOR MANUFACTURE OF WHOLE BLOOD COMPONENTS

NOTE: This report is mandated by Section 351 of the Public Health Service Act; the Federal Food, Drug and Cosmetic Act, Section 502 and Title 21, CFR Part 600. No license can be granted unless this completed application form has been received.

1. MANUFACTURER'S NAME, ADDRESS, AND ZIP — TELEPHONE NO. *(Include Area Code)*

2. ESTABLISHMENT NAME, ADDRESS, AND ZIP CODE *(If different from item 1)* PROVIDE INFORMATION ON ALLOCATIONS APPLYING FOR A WHOLE BLOOD LICENSE. — TELEPHONE NO. *(Include Area Code)*

3. TYPE OF APPLICATION *(Check one)* ☐ ORIGINAL ☐ AMENDED

4. THIS LICENSE APPLICATION IS FOR:

WHOLE BLOOD
- ☐ ACD
- ☐ CPD
- ☐ CPDA-1
- ☐ HEPARIN
- ☐ FOR FURTHER MANUFACTURING
- ☐ OTHER

WHOLE BLOOD, MODIFIED*
- ☐ PLATELETS REMOVED
- ☐ LEUKOCYTES REMOVED
- ☐ CRYOPRECIPITATED ANTIHEMOPHILIC FACTOR REMOVED

*If whole blood, modified is prepared, submit a copy of your procedure for preparing this project

5. INDICATE THE STANDARD OPERATING PROCEDURES MANUAL USED:
☐ AABB ☐ ANRC ☐ OWN ☐ OTHER APPROVED ORGANIZATION *(Specify)* _____

A COPY OF THE STANDARD OPERATING PROCEDURES MANUAL WHICH INCLUDES CURRENT DIRECTIONS FOR ALL PROCEDURES PERFORMED PERTINENT TO THE MANUFACTURE OF THESE PRODUCTS IS MAINTAINED ON THE PREMISES OF EACH LOCATION; RECORDS DOCUMENTING EACH STEP IN MANUFACTURE ARE PREPARED CONCURRENTLY AND MAINTAINED AT LEAST 5 YEARS.
☐ YES ☐ NO

6a. ROUTINE LABORATORY TEST PROCEDURES FOR ABO AND Rh GROUPING *(INCLUDING D^{u})* AND ANTIBODY SCREENING ARE PERFORMED MANUALLY USING LICENSED REAGENTS IN CONFORMANCE WITH THE MANUFACTURER'S WRITTEN DIRECTIONS FOR USE.
☐ YES ☐ NO
IF NO, SEE ATTACHMENTS CONCERNING INFORMATION TO BE SUBMITTED,

b. TEST FOR HEPATITIS IS PERFORMED BY:
☐ RIA ☐ RPHA ☐ RPLA ☐ OTHER _____
IF THIS TEST IS NOT PERFORMED ON THE PREMISES, GIVE THE NAME AND ADDRESS OF ESTABLISHMENT WHERE THE TEST IS PERFORMED AND SUBMIT A COPY OF A TEST RESULT REPORT AND THE WRITTEN AGREEMENT PERMITTING FDA TO INSPECT THE TESTING LABORATORY.

c. LIST OTHER TESTS ROUTINELY PERFORMED.

7. BLOOD DONATION IS RESTRICTED TO NO MORE THAN _____ ml AT INTERVALS OF _____ WEEKS OR LONGER AND NO MORE THAN _____ TIMES PER YEAR.

ITEM	YES	NO
8. THE DONORS' MEDICAL HISTORY AND PHYSICAL DATA ARE AS SPECIFIED BY THE REGULATIONS AND ARE RECORDED IMMEDIATELY PRECEDING EACH PHLEBOTOMY.		
9. IF LICENSED PHYSICIAN IS NOT PRESENT DURING DONOR SCREENING BLOOD COLLECTION, A RECORD OF THE NAME AND QUALIFICATIONS OF THE PERSON IMMEDIATELY IN CHARGE IS MAINTAINED.		
10. PREPACKAGED SUPPLIES USED FOR PREPARING THE PHLEBOTOMY SITE? LIST SUPPLIES USED. IF PREPACKAGED SUPPLIES ARE NOT USED, ATTACH A DESCRIPTION OF PROCEDURE FOR PREPARING SUPPLIES AND PERFORMING THE ARM PREPARATION.		
11. BLOOD IS COLLECTED BY SINGLE VENIPUNCTURE, IN A CLOSED SYSTEM, WITH MIXING ADEQUATE TO PREVENT CLOTTING, IN A CONTAINER IDENTIFIED WITH DONOR UNIT NUMBER PRIOR TO COLLECTION.		
12. THE EXPIRATION DATE ASSIGNED TO THE WHOLE BLOOD IS NO MORE THAN: ACD, 21 DAYS; CPD, 21 DAYS; CPDA-1, 35 DAYS; HEPARIN, 48 HOURS; UNITS DIVIDED IN AN OPEN SYSTEM, 24 HOURS.		
13. PROCESSING SAMPLES ARE COLLECTED AT THE TIME OF WHOLE BLOOD COLLECTION.		

ITEM	YES	NO
14. HB_sAg POSITIVE REAGENTS ARE SEGREGATED FROM BLOOD UNITS, HB_sAg POSITIVE BLOOD UNITS ARE AUTOCLAVED OR INCINERATED AND ALL HB_s Ag TESTING EQUIPMENT, REAGENTS AND SUPPLIES ARE DISPOSED OF SAFELY.		
15. IMMEDIATELY FOLLOWING COLLECTION BLOOD IN TRANSIT IS COOLED TOWARD A TEMPERATURE OF 1-10° C (or 20 - 24° C FOR 4 HOURS IF PLATELETS PREPARED); BLOOD IS STORED AT 1-6° C, AND IS MAINTAINED AT 1-10° C DURING SHIPMENT AS DOCUMENTED BY QUARTERLY TESTS (3 MONTH INTERVALS).		
16. PRECAUTIONS ARE TAKEN TO PREVENT LABELING ERRORS AND RELEASE OF PRODUCTS NOT SAFE FOR TRANSFUSION.		
17. BLOOD IS NOT REISSUED UNLESS THE APPEARANCE IS NORMAL, THE BAG SEAL UNBROKEN AND RECORDS DOCUMENT PROPER STORAGE TEMPERATURE IF THE BLOOD WAS OUT OF THE BLOOD BANK FOR MORE THAN 30 MINUTES.		

IF **NO** IS CHECKED FOR ANY OF THE ITEMS IN 8-17, ATTACH DETAILED EXPLANATION.

CERTIFICATION

I certify that there is documentation in the records which supports that, for each unit of the products covered in this application, all critical manufacturing steps have been performed in accordance with current Federal Regulations, and that the responsible individual has signed the pertinent manufacturing records on the day of manufacture.

I also certify that all statements made in this application are true and complete to the best of my knowledge and ability. I am familiar with the pertinent Sections of Part 600-640 of Title 21, Code of Federal Regulations, and am aware of my responsibilities described therein.

WARNING: A willfully false certification is a criminal offense. U.S. Code, Title 18, Section 1001.

TYPED NAME OF RESPONSIBLE HEAD	SIGNATURE	DATE

ATTACHMENTS

A. Samples of complete labeling (including all overlays and circular with directions for use) for all products checked in item 4. If ARC/AABB circular is used without modification, submit only one copy.

Labels should be submitted on Form FDA 2567, "Transmittal of Labels and Circulars," in triplicate and may be mock-ups or printer's proofs.

B. Procedures for preparing Whole Blood, Modified, if applicable.

C. Procedures for laboratory testing utilizing the auto Analyzer, Groupamatic or Microtiter techniques (item 6a), if applicable.

NON-STANDARD LABORATORY PROCEDURES (Application item 6a)

IF ABO or Rh grouping tests or antibody screening tests are not performed manually using licensed reagents in conformance with the manufacture's written directions for use, additional information concerning your procedures must be submitted to the center.

List the procedures used for ABO, D, D^u, and Antibody Screening Tests.

1. At least 500 samples should be tested by an approved procedure in parallel with new procedure prior to application for license. A detailed record of any discrepant results must be maintained; a brief summary of your experience including identification of each problem and how it was resolved should be submitted.

2. If reagents which are not licensed for use in your procedure are utilized, the procedures which will be used in your laboratory to evaluate each reagent lot must be described in the SOP. Submit a copy of this Section of the SOP and actual test results for reagents used in the parallel studies. In general, you will be required to demonstrate that each lot of reagent is potent and specific when used by your techniques. Control testing should include examples of weekly reactive phenotypes. Control samples may be fresh or frozen-thawed cells. If reagents are used at varying dilutions, the protocol should clearly indicate how the correct dilution is selected for use of a new lot.

3. A copy of the SOP for routine test performance including daily quality control procedures should be submitted. At least one positive and one negative control samples should be used daily to verify that each reagent is giving expected results.

4. If your techniques are based on a published method, please cite the appropriate references. If you are using a Groupamatic or Auto-Analyzer machine, it is not necessary to submit copies of the equipment manufacturer's SOP as these are already on file with the Center. Identify any of your procedures that differ from the manufacturer's SOP.

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